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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,164	04/23/2001	Vladimir Kozlov	1331-338	6786

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
CARLSON, KAREN C	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/839,164	KOZLOV ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *03 December 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *30-32*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Applicants continue to argue tht the Examiner has cited no legal authority regarding why claims drawn to a mass amount of a globin of hemoglobin is not a permissible claim limitatio. As stated previously by the Examiner, standard chemicla nad pharmaceutical pracitce will prevail. Applicants do not refute that pharmaceutical compositions are routinely presented as concentrations. Indedd, in the final action, the Examienr notd that the Applicants may be wanting to admiister -.1 mg - 6 g globin chain in a single dose. If that is what Applicants want, then claim it accordingly, being careful not to add new matter. Indeed, deletion of the recitation of the mass altogether would overcome this rejection of the claims under 112, 2. Applicants urge that Tame et al. do not cisclose a solution containing -.1 mg- 6 g globin chain because Tame et al. recite the solutions as concentrations. The burden falls to applicatns to prove that the globin solutions of Tame et al. do not meet their own claimed mass limitations. Applicants argue that Hoffman et al. do not disclose a composition of the recited globin chain mass and that such a solution comprising 0.1mg - 6 g globin chain is impermissible. Without a volune recited in the claims, Hoffman et l. continues to anticipate the claims. The burden falls to applicatns to prove that the globin solutions of Tame et al. do not meet their own claimed mass limitations. At page 3, Applicants urge that both Tame et al. and Hoffman et al. produced the globin chains in E.coli and the purification of the globin chains did not remove endotoxins; thus, the buffer solutions of Tame et al. and of Hoffman et al. are not suitable for sc administration. At page 17 of the specification, such expression in E. coli is a prefered embodiment: --- In an advantageous embodiment, IMPROL is the product of prokaryotic or eukaryotic host expression (e.g., by bacterial, yeast. higher plant. insect and mammalian cells in culture) of exogenous DNA sequences obtained by genomic or cDNA cloning or by gene synthesis. that is, in an advantageous embodiment INPRO is "recombinant INPROL". The product of expression in typical yeast (e.g., Saccharomyces cerevisiae) or prokaryote (e.g., E. coli) host cells are free of association with any mammalian proteins. Tne products of expression in vertebrate (e-g-,non-human mnmmalian (e.g., COS or CHO) and avian) cells are free of association with any human proteins. Depending on the host employed. polypeptides of the invention may be glycosylated or may be non-glycosylated. Polypeptides of the invention optionally also include an initial methionine amino acid residue (at position -1). ---- Therefore, this argument is not persuasive because the specification states that it is desireable to express the globin chains in E. coli.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER